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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,662

02/25/2004

John D. Maynard

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08/11/2004

InLight Solutions, Inc.
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800 Bradbury SE
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EXAMINER

KREMER, MATTHEW J

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/786,662

Applicant(s)

MAYNARD ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-20 and 23-29 is/are rejected.
- 7) ☒ Claim(s) 8-9 and 21-22 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/18/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objections

1. Claims 6, 19, and 28 are objected to because of the following informalities.

Claim 6 is identical to claim 5. Claim 19 is identical to claim 18. The word "on" in claim 28, line 4 should be "one". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "infrared radiation" in claims 7 and 20 is used by those claims to mean "radiation in the spectral frequency range from 4000-25000 cm^{-1} ", while the accepted meaning of infrared radiation does not extend above 12500 cm^{-1} . (see Fig. 1 of U.S. Patent 6,178,346 to Amundson et al.). In other words, the Applicant is trying to expand the definition of

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infrared radiation to include the visible spectrum. The term is indefinite because the specification does not clearly redefine the term. For the purposes of examination, the term "infrared radiation" was interpreted with its accepted meaning of infrared radiation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-7, 10-20, and 23-29 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,885,212 to Scharlack. In regard to claims 1 and 14, Scharlack teaches a method of determining blood pH by a multivariate analysis technique. (Abstract of Scharlack). Scharlack teaches that the concentration of hemoglobin is determined. (column 5, lines 18-38 of Scharlack). Scharlack teaches the use of infrared spectrum in the form of wavelengths up to 900 nm. (column 2, lines 25-33 of Scharlack). In regard to claims 2-4 and 15-17, regression coefficients are determined from calibration samples and used since classical least squares, partial least squares, or principal components regression is used. (Abstract of Scharlack). In

regard to claims 5-6 and 18-19, transmission or reflectance measurements are used. (column 3, lines 58-64 of Scharlack). In regard to claims 7 and 20, Scharlack teaches the use of the infrared spectrum in the form of wavelengths up to 900 nm. (column 2, lines 25-33 of Scharlack). In regard to claims 11 and 24, the concentration of hemoglobin is taken from noninvasive measurement of perfused tissue. In regard to claims 12 and 25, the measurements are averaged over multiple measurements to reduce errors. (column 3, lines 42-50 of Scharlack). In regard to claims 13 and 26, the sample comprises perfused tissue. In regard to claim 14, the step of verifying that the spectrum is spectrally consistent with the calibration model is inherent in the selection of the specific wavelengths for use in the method. In regard to claims 27-28, Scharlack teaches that the device in U.S. Patent 5,355,880 to Thomas et al. (Thomas) is used. (column 2, lines 45-49 of Scharlack). Thomas teaches an illumination system that includes a broadband tungsten halogen light source 19; an illumination system and collection system that includes optical fibers 73 and 77; and an analysis system in the form of a computing unit 15. (Fig. 1 of Thomas). In regard to claim 28, it is noted that the limitations "hemoglobin concentration is determined using radiation in the spectral frequency range from 10,000 - 25,000 cm^{-1} " and "pH is determined using radiation in the spectral frequency range from 4,000 - 10,000 cm^{-1} combined with the hemoglobin concentration" do not add any further structural limitations to the claimed apparatus since they are method steps. In regard to claim 29, Scharlack teaches a means for determining the infrared spectrum (Fig. 1 of Thomas), a means for determining the concentration of hemoglobin (column 5, lines 18-29 of Scharlack), and a means for

determining the pH of the sample (column 5, lines 30-44 of Scharlack). The means for selecting a model relating an infrared spectrum to pH is inherent in the system since a particular model is used, which implies that it was selected for use.

6. Claim 27 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2003/0109772 to Mills. Mills teaches an apparatus for determining pH that includes an illumination system and collection system (Figs. 5 and 8 of Mills) and an analysis system (Fig. 11 and 14 of Mills) that comprises a model for determining sample pH from radiation expressed and a hemoglobin concentration (paragraphs 0298 and 0306 of Mills).

Allowable Subject Matter

7. Claims 8-9 and 21-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter. In regard to claim 8, the prior art does not teach or suggest the step of “determining an infrared spectrum comprises measuring the sample absorbance of infrared radiation in the spectral frequency range from 4000-8000 cm^{-1} ” that is combined or combinable with the other limitations of claim 8. In regard to claim 9, the prior art does not teach or suggest the step of “determining an infrared spectrum comprises

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measuring the sample absorbance of infrared radiation in the spectral frequency range from $6000 - 6500 \text{ cm}^{-1}$ that is combined or combinable with the other limitations of claim 9. In regard to claim 21, the prior art does not teach or suggest the step of “determining an infrared spectrum comprises measuring the sample absorbance of infrared radiation in the spectral frequency range from $4000 - 8000 \text{ cm}^{-1}$ ” that is combined or combinable with the other limitations of claim 21. In regard to claim 22, the prior art does not teach or suggest the step of “determining an infrared spectrum comprises measuring the sample absorbance of infrared radiation in the spectral frequency range from $6000 - 6500 \text{ cm}^{-1}$ ” that is combined or combinable with the other limitations of claim 22.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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